EFED FILE COPY

MRID No. 444577-81

DATA EVALUATION RECORD
§ 141-1 - HONEY BEE ACUTE CONTACT AND ORAL LD_{50} TEST

1. **CHEMICAL:** Prohexadione calcium — PC Code No.: 112600

2. **TEST MATERIAL:** BX-112 technical — Purity: 93.3%

3. **CITATION:**

Author:	J.H. Cole
Title:	The Acute Contact and Oral Toxicity to Honey Bees of Technical BX-112
Study Completion Date:	April 17, 1997
Laboratory:	Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England
Laboratory Report ID:	KCI 31/891511
Sponsor:	BASF Corporation, Research Triangle Park, NC
DP Barcode:	D245631
MRID No.:	444577-81

4. **REVIEWED BY:** Mark Mossler, M.S., Toxicologist, Golder Associates Inc.

Signature: **Date:**

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist, Golder Associates Inc.

Signature: **Date:**

5. **APPROVED BY:** Brian Montague, Fisheries Biologist

Signature: Brian Montague **Date:** 7/13/99

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Apis mellifera*
Definitive Study Durations: 48 hours

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements. The acute contact and oral LD_{50} were both >100 µg/bee. These values classify the test material as practically non-toxic to *Apis mellifera*. The NOEL values for the oral and contact tests could not be determined due to treatment mortality that was greater than control mortality.

8. **ADEQUACY OF THE STUDY:**
   - **A. Classification:** Core
   - **B. Rationale:** N/A
   - **C. Repairability:** N/A

DATA EVALUATION RECORD
§ 141-1 - HONEY BEE ACUTE CONTACT AND ORAL LD_{50} TEST

1. **CHEMICAL:** Prohexadione calcium — PC Code No.: 112600

2. **TEST MATERIAL:** BX-112 technical — Purity: 93.3%

3. **CITATION:**

Author:	J.H. Cole
Title:	The Acute Contact and Oral Toxicity to Honey Bees of Technical BX-112
Study Completion Date:	April 17, 1997
Laboratory:	Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England
Laboratory Report ID:	KCI 31/891511
Sponsor:	BASF Corporation, Research Triangle Park, NC
DP Barcode:	D245631
MRID No.:	444577-81

4. **REVIEWED BY:** Mark Mossler, M.S., Toxicologist, Golder Associates Inc.

Signature: [signature] **Date:** 7/1/98

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist, Golder Associates Inc.

Signature: P. Kosalwat **Date:** 7/1/98

5. **APPROVED BY:**

Signature: [signature] **Date:** 10/20/98

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Apis mellifera*
Definitive Study Durations: 48 hours

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements. The acute contact and oral LD_{50} were both >100 µg/bee. These values classify the test material as practically non-toxic to *Apis mellifera*. The NOEL values for the oral and contact tests could not be determined due to treatment mortality that was greater than control mortality.

8. **ADEQUACY OF THE STUDY:**

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

1. Age of the test bees was not reported.

2. The number of bees (10) per replicate (cage) was less than recommended (25 bees per replicate). However, ten cages were used per group.

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Honey bee (*Apis mellifera*)	*Apis mellifera*
Age at beginning of test: Worker bees of uniform age.	Worker bees
Supplier	Mr. R. Baker, St. Ives, Cambridgeshire, England
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Yes
Lighting: Bees should be maintained in the dark.	Bees maintained in the dark
Temperature: 27°C (80°F).	24 ±1°C
Relative humidity: Approx. 65%	Not reported

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, bees tested at 0.01, 0.1, 1, 10, and 100 µg/bee both orally and topically
Reference toxicant tested?	No
Method of administration: Whole body exposure in a nontoxic dust diluent; or topical exposure via microapplicator.	Contact test: Topical exposure on ventral thorax via micropipette (in DMF) Oral test: Dose administered for 4 hours via suspension in DMF and mixing with food (20% sucrose solution) followed by "clean" food
Nominal doses: Sufficient number of dosage levels to yield statistically sound data unless it can be determined that the LD_{50} will be greater than 25 µg/bee.	Nominal concentration 100 µg/bee for both tests
Controls: Negative control and/or diluent/solvent control	Diluent and vehicle/diluent controls for the contact and oral tests, respectively
Number of bees per cage: 25 (recommended)	10 bees per cage (both tests)
Number of cages per group: 3 replicate cages per group is recommended.	10 cages per treatment group and 2 cages per control group
Carrier: Non-toxic dust (e.g, Pyrolite).	N/A
Solvent: Distilled water or the following solvents: dimethyl-formamide, triethylene glycol, methanol, acetone, ethanol.	DMF
Volume of test solution: ≤2 µl/bee (for contact tests).	Contact test: 1 µl drop Oral test: approximately 20 µL/bee

Guideline Criteria	Reported Information
Observations period: At least 48 hours.	48 hours for both tests

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Controls: Mortality not more than 15%	0% for all control groups
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of toxicity were reported

Mortality - Contact Test

Applied Dosage (µg/bee)	No. of Bees	Cumulative Number of Dead Bees	
		Hour of Study	
		24	48
Sol. Con.	20	0	0
100	100	2	6

Mortality - Oral Test

Ingested Dosage (µg/bee)	No. of Bees	Cumulative Number of Dead Bees	
		Hour of Study	
		24	48
Sol. Con.	20	0	0
100	100	7	12

Other Significant Results: It was stated that the material is of low toxicity to bees on an oral and contact basis.

Reported Statistical Results - Contact Test

Statistical Method: Visual inspection
LD_{50}: >100 µg/bee 95% C.I.: N/A
NOEL: Not reported Probit Slope: N/A

Reported Statistical Results - Oral Test

Statistical Method: Visual inspection
LD_{50}: >100 µg/bee 95% C.I.: N/A
NOEL: Not reported Probit Slope: N/A

13. **VERIFICATION OF STATISTICAL RESULTS:** The magnitude of dose response in both tests precluded the use of statistical analyses.

14. **REVIEWER'S COMMENTS:** This study is scientifically sound, fulfills the guideline requirements for honey bee acute contact and oral toxicity tests, and can be classified as **Core.** The acute contact and oral LD_{50} were both >100 µg/bee. This value classifies prohexadione calcium as practically non-toxic to *Apis mellifera*. The NOEL values for the oral and contact tests could not be determined due to treatment mortality that was greater than control mortality.